Applicants gratefully acknowledge the Examiner's indication that claims 9-25, 32-35 and 45-69 are allowable over the prior art of record. In the Office Action, claims 9-25, 32-41 and 43-82 have been rejected. Claims 9, 45 and 50 are amended herein, and claims 83 and 84 are added, purely to clarify the subject matter of the invention. Claims 9-25, 32-35, 45-69, 83 and 84 are pending in this matter.

The foregoing claim amendments are intended to clarify the inventive subject matter and thereby overcome the rejections under 35 U.S.C. § 112, first and second paragraphs and 35 U.S.C. § 101. A Terminal Disclaimer is filed herewith to obviate the rejection based on the grounds of nonstatutory double patenting.

No new matter is submitted by these claim amendments and no new issues are raised by the claim amendments. Accordingly, applicants respectfully submit that the claim amendments and newly added claims should be entered.

Applicants will file a supplemental submission to provide the Examiner with the information requested in the Office Action with regard to the Information Disclosure Statement, as appropriate.

I. PATENTABLE UTILITY

Claims 45-69 are rejected under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, as lacking patentable utility and for lack of enablement based thereon. In particular, the Examiner alleges that claims 45-69 "do not require that any polypeptide substance have any enzymatic activity and the specification does not disclose that any substance not a polypeptide is capable of exhibiting hexose oxidase activity." See Office Action, page 4.

Applicants respectfully submit that the claims prior to their amendment herein did not lack patentable utility because the specification provides substantial disclosure regarding the utility of the claimed subject matter. Nonetheless, Applicants amended their claims in an effort to expedite prosecution of the application. The foregoing

amendments are intended merely to clarify the patentable utility of the claims and are not related to patentability of the claims.

In particular, claim 45 has been amended to clarify that the claimed "substance" comprises a polypeptide having hexose oxidase activity. As noted by the Examiner, "had Applicant intended that claims 45-69 describe compositions comprising polypeptides having hexose oxidase activity, amending claims 45-69 to describe such compositions will avoid this rejection." Office Action , page 5. The recitation of the claims is therefore consistent with the suggestion of the Examiner.

In view of the foregoing, the claims clearly recite a patentable utility. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 45-69 under 35 U.S.C. § 101 for lack of patentable utility and under 35 U.S.C. § 112, first paragraph, for lack of enablement based upon said lack of patentable utility.

II. THE WRITTEN DESCRIPTION REQUIREMENT IS SATISFIED

Claims 9-25, 32-35 and 45-69 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

At the outset, applicants respectfully point out that the initial burden of establishing a basis for denying patentability of a claimed invention rests upon the Patent Office. *See In re Fine*, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). It is equally well established that the Patent Office bears the initial burden to establish a reasonable basis to question the written description provided in the specification for the invention defined in Applicants' claims. *See In re Wright*, 27 U.S.P.Q.2d 1510 (Fed. Cir. 1993).

Applicants respectfully traverse the Examiner's rejection for the following reasons. Applicants' full scope of claimed subject matter was described in such a way

as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, even prior to the amendment of the claims herein. Applicants have amended their claims merely to clarify the subject matter of the claims and not for reasons related to patentability as is further explained below.

It is well established that a disclosure of the specification provides a description of the claimed subject matter if it reasonably conveys to persons skilled in the art that the inventor has possession of that subject matter at the time the application was filed. *See, e.g., Fujikawa v. Wattanasin*, 39 U.S.P.Q.2d 1895 (Fed. Cir. 1996) and *Vas-Cath, Inc.v. Mahurkar*, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). Applicants respectfully submit that their specification, as filed, satisfied that standard because persons of ordinary skill in the art, familiar with applicants' specification, would clearly understand that they possessed the claimed subject matter. This is indicated, for example, by the Examiner's appreciation of the full scope of Applicants' claimed invention in the Office Action.

In the Office Action, the Examiner asserts that the claims "reach generic polypeptides, or substances, comprising a polypeptide which, itself, cannot be expected to support the functional limitation." See Office Action, page 5. However, under the current Written Description Guidelines of the U.S. Patent and Trademark Office (Patent Office), one way in which the written description requirement for a claimed genus may be satisfied is by disclosure of "relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus." 66 *Fed. Reg.* 1099, 1106 (2001). Here the claims specifically recite structural characteristics (i.e., specific sequences, SEQ ID NO:3 in particular) and functional characteristics (i.e. hexose oxidase activity) and that this is coupled with a "disclosed correlation between function and structure" (the Specification clearly

discloses a correlation between the recited structures and hexose oxidase activity, see Example 4, pages 64-72, Example 5, pages 73-75 and Example, 6, pages 75-77). Therefore, based upon the Patent Office's own Guidelines, the specification satisfies the written description requirement.

Further, the Examiner alleges that "[n]either the claims nor the specification describe the design of such generic proteins nor any location therein of the peptide of SEQ ID NO:3 and the specification does not otherwise disclose or suggest the nature or source of any of the generic proteins that meet the limitations of the claims." Office Action, page 5. As the Written Description Guidelines specify, one of the factors to be considered in determining if the written description requirement is satisfied is whether a representative number of species is disclosed in the specification. (See Guidelines, page 9). A representative number of species is disclosed if one skilled in the art would recognize that applicant possessed the necessary common attributes or features of the elements of the members of the genus in view of the species disclosed and claimed. *Id.*

As clearly demonstrated by a review of the specification, applicants do indeed disclose such a representative number of species. See, for instance, Example 4, at pages 64-72, Example 5, pages 73-75 and Example, 6, pages 75-77.

In view of the foregoing comments, it is clear that the original claims satisfy the written description requirement. Nonetheless, as previously indicated, in the interest of advancing prosecution, applicants have amended their claims. Specifically, Applicants deleted the phrase "and muteins and variants thereof" merely to clarify the subject matter of the invention and not for reasons related to patentability. Therefore, Applicants' claimed subject matter continues to be described in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In view of the foregoing, a person skilled in the art would reasonably conclude that applicants were indeed in possession of the claimed invention. Accordingly,

Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

III. THE ENABLEMENT REQUIREMENT IS SATISFIED

It is well established that the test for enablement is whether one of ordinary skill in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988); see also *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988).

In the Office Action, the Examiner rejects claims 9-25, 32-35 and 45-69 as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected to make and/or use the invention. The Examiner correctly states that the specification is "enabling for a polypeptide having hexose oxidase activity and comprising the amino acid sequence set forth in SEQ ID NO:31." Office Action, page 5. However, the Examiner misapprehends the specification when he alleges that the specification "does not reasonably provide enablement for the preparation or use of a generic polypeptide, or a generic substance, that comprises no more definite structure than a polypeptide having the sequence of sixteen amino acids of SEQ ID NO:3." Office Action, page 5.

Applicants respectfully point out that the Specification contains substantial disclosure regarding specific primers, oligonucleotides, etc. and general and specific procedures for preparing the claimed polypeptides. For example, Table 3.1 on page 56 discloses the DNA sequences of the primers used in DNA sequencing or in PCR, and there is a general description of the techniques used on pages 9-14. Accordingly, a person skilled in the art, guided by such disclosures would be able to make and/or use the claimed class of polypeptides, without undue experimentation. In *In re Wands*, the

Federal Circuit held that the specification was enabling with respect to the claims at issue because "there was considerable direction and guidance in the specification". *Id.* Here, as in Wands, there is considerable direction and guidance in the specification.

Therefore, it is submitted that a person of ordinary skill in the art can practice the full scope of the claimed subject matter without having to conduct any undue experimentation. Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

IV. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 45-69 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner alleges that "it is not clear what had been intended by the preamble of claim 45, '[a] substance having hexose oxidase activity', particularly where the substance in the remainder of the claim is a polyacrylamide gel comprising the chaotropic agent, sodium dodecyl sulfate, and a polypeptide wherein presence of the chaotrope must, of necessity, disable any enzymatic activity of any polypeptide in the gel." See Office Action, page 8.

Applicants submit that the claims prior to their amendment herein were definite because persons skilled in the art would have been readily able to ascertain the scope of the claimed invention. For example, the claims clearly do not recite a substance comprising polyacrylamide gel, but instead recite a substance comprising a polypeptide that is "characterized" by 29kD or 40kD bands with SDS-PAGE. Nonetheless, Applicants have amended their claims in an effort to expedite prosecution of the application. The amendments are intended merely to add consistency to certain portions of the claims, and they are not related to patentability of the claims. Thus, the amended claims continue to satisfy the definiteness requirements of 35 U.S.C. § 112, second paragraph.

Specifically, claim 45 has been amended to clarify that the claims are intended to describe compositions comprising a polypeptide having hexose oxidase activity by removing the phrase "having hexose oxidase" from the preamble and reciting the phrase in the body of the claim. Further, claim 45 has been amended to recite a singular mass characteristic (i.e., either one of two mass characteristics, as determined by SDS-PAGE, recited in the claims) by clarifying that the polypeptide is "characterized by a band at 29 kD or 40 kd as determined by Sodium Dodecyl Sulphate-Polyacrylamide Gel Electrophoresis (SDS-PAGE)." The examples of the Specification provide clear support for these clarifying amendments.

Applicants believe that the foregoing amendments to claim 45 are consistent with the Examiner's indication in the Office Action that "amending these claims to describe (a) composition(s) that comprises a disclosed hexose oxidase with a singular mass characteristic will overcome this rejection." See Office Action, page 8. Therefore, Applicants believe that the rejection under 35 U.S.C. § 112, second paragraph is obviated by the amendments.

Accordingly, Applicants respectfully submit that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. § 112, second paragraph. The Examiner is welcomed to telephone the undersigned if any issues remain outstanding.

V. OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION

Claims 45-65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25 and 26 of U.S. Patent No. 6,251,626. Applicants respectfully submit that the attached Terminal Disclaimer obviates the Examiner's basis for this rejection of claims 45-65.

REQUEST FOR ALLOWANCE

For at least the reasons detailed above, applicants respectively submit that all of the claims in the application are patentable. Favorable consideration, entry of this amendment, and issuance of a notice of allowance are respectively requested.

If any issues remain, the Examiner is encouraged to contact applicants' representatives to resolve such issues in an expeditious manner, and place the application in condition for allowance.

In the event any fees are incurred upon the filing of these documents, please charge the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS

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APPENDIX

9. (Amended) A polypeptide in isolated form having hexose oxidase activity, comprising at least one amino acid sequence selected from the group consisting of

(i) Tyr-Glu-Pro-Tyr-Gly-Gly-Val-Pro (SEQ ID NO:1),

(ii) Ala-Ile-Ile-Asn-Val-Thr-Gly-Leu-Val-Glu-Ser-Gly-Tyr-Asp-X-X-X-Gly-Tyr-X-Val-Ser-Ser (SEQ ID NO:2),

(iii) Asp-Leu-Pro-Met-Ser-Pro-Arg-Gly-Val-Ile-Ala-Ser-Asn-Leu-X-Phe (SEQ ID NO:3),

(iv) Asp-Ser-Glu-Gly-Asn-Asp-Gly-Glu-Leu-Phe-X-Ala-His-Thr (SEQ ID NO:4),

(v) Tyr-Tyr-Phe-Lys (SEQ ID NO:5),

(vi) Asp-Pro-Gly-Tyr-Ile-Val-Ile-Asp-Val-Asn-Ala-Gly-Thr-X-Asp (SEQ ID NO:6),

(vii) X-Ile-Arg-Asp-Phe-Tyr-Glu-Glu-Met (SEQ ID NO:8),

where X represents an amino acid selected from the group consisting of Ala, Arg, Asn, Asp, Asx, Cys, Gln, Glu, Glx, Gly, His, Ile, Leu, Lys, Met, Phe, Pro, Ser, Thr, Trp, Tyr and Val[, and muteins and variants hereof].

45. (Amended) A substance [having hexose oxidase activity] comprising:

a polypeptide <u>having hexose oxidase activity, said polypeptide being characterized by a band at 29 kD or 40 kD as determined</u> [characterized] by Sodium

Dodecyl Sulphate-Polyacrylamide Gel Electrophoresis (SDS-PAGE) [as showing separate bands at 29 kD and 40 kD].

50. (Amended) A substance according to claim 45, wherein the polypeptide comprises at least one amino acid sequence selected from the group consisting of

(i) Tyr-Glu-Pro-Tyr-Gly-Gly-Val-Pro (SEQ ID NO:1),

(ii) Ala-Ile-Ile-Asn-Val-Thr-Gly-Leu-Val-Glu-Ser-Gly-Tyr-Asp-X-X-X-Gly-Tyr-X-Val-Ser-Ser (SEQ ID NO:2),

(iii) Asp-Leu-Pro-Met-Ser-Pro-Arg-Gly-Val-Ile-Ala-Ser-Asn-Leu-X-Phe (SEQ ID NO:3),

(iv) Asp-Ser-Glu-Gly-Asn-Asp-Gly-Glu-Leu-Phe-X-Ala-His-Thr (SEQ ID NO:4),

(v) Tyr-Tyr-Phe-Lys (SEQ ID NO:5),

(vi) Asp-Pro-Gly-Tyr-Ile-Val-Ile-Asp-Val-Asn-Ala-Gly-Thr-X-Asp (SEQ ID NO:6),

(vii) X-Ile-Arg-Asp-Phe-Tyr-Glu-Glu-Met (SEQ ID NO:8),

wherein X represents an amino acid selected from the group consisting of Ala, Arg, Asn, Asp, Asx, Cys, Gln, Glu, Glx, Gly, His, Ile, Leu, Lys, Met, Phe, Pro, Ser, Thr, Trp, Tyr and Val[, and muteins and variants hereof].